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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,825	01/15/2002	Rodrigo F. Chaqui	66043	8611

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,825	CHAQUI ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-8,10-19,25 and 27-34* is/are pending in the application.

4a) Of the above claim(s) *6-8,13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,10-12,17-19,25 and 27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous Office action has been withdrawn, and the prosecution of this application is reopened to include rejections not previously cited.

It is noted that applicant has paid for a Notice of Appeal. Applicant can either request a refund or place the funds on credit for future appeals.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 20-24, 26, 35-40.

Accordingly, claims 2-3, 5, 10-12, 17-19, 25, 27-34, SEQ ID NO:1, 7-8 and 10, are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 5, 18 are indefinite for the use of the language "hybridizes specifically" in claim 18.

It is noted that "hybridizes specifically", which is not defined by the claims, encompasses hybridizes under a full range of specificity, from very low specificity to very high specificity. The specification does not provide a standard for ascertaining the requisite degree of specificity and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION, NEW REJECTION

Claim 17 and dependent claims 2-3, claim 18, claim 19 and dependent claims 10-11, 25, claim 27 and dependent claims 28-29, claim 30 and dependent claims 31-34 are rejected under 112, first paragraph for lack of a clear written description of the claimed nucleic acids.

Claim 17 and dependent claims 2-3, claim 18, claim 19 and dependent claims 10-11, 25, claim 27 and dependent claims 28-29, claim 30 and dependent claims 31-34 are drawn to:

a) A nucleic acid that "comprises" a sequence that is completely complementary to the sequence of SEQ ID NO:1 (claims 2, 3, 17), or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1 (claims 27-29), and

A method for detecting prostate cancer, comprising detecting an increased content of said nucleic acid (claims 10-11, 19, 25, 30-34).

b) A nucleic acid molecule that consist of a fragment of SEQ ID NO:1, wherein said fragment hybridizes specifically with a nucleic acid molecule "having" a sequence that is completely complementary to SEQ ID NO:1 (claim 18),

It is noted that the language "having" in claim 18 is interpreted as having the same meaning as the open language "comprises".

Due to the language "having" or "comprises', the claims 2-3, 17-18, 27-29 encompass unknown sequences that are attached to a sequence of any size, wherein the full length of said sequence of any size is completely complementary to the

sequence of SEQ ID NO:1, or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1.

The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because a complementary fragment of SEQ ID NO:1, or of the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1 is only a fragment of any full-length gene or cDNA species. "A nucleic acid molecule comprising a sequence that is completely complementary to SEQ ID NO:1, or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1" encompasses a variety of subgenera with widely varying attributes . For example,a cDNA 's principle attribute would include its coding region.A partial cDNA that did not include a disclosure of any open reading frame (ORF)of which it would be a part,would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed.

The instant specification does not describe the claimed nucleic acids in a manner that satisfies the standards as set forth in the example of Lilly and Enzo. The specification fails to describe "a representative number of species". The specification only describes a single polynucleotide, SEQ ID NO:1 and its primers of consisting of SEQ ID NO:7, 8 or 10. In addition, the specification does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus". The specification also fails to describe characteristics coupled with known or disclosed correlation between function and structure.

One would reasonably conclude that Applicant did not have possession of the claimed nucleic acids at the time of filing. Further, since the specification fails to adequately describe the product that is used in the claimed method, it also fails to adequately describe the claimed method.

Thus the specification and the claims do not meet the 112, first paragraph, written description requirement.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION

Claim 17 and dependent claims 2-3, claim 18, claim 19 and dependent claims 10-11, 25, claim 27 and dependent claims 28-29, claim 30 and dependent claims 31-34 are rejected under 35 U.S.C. 112, first paragraph

A. Claims Claim 17 and dependent claims 2-3, claim 18, claim 19 and dependent claims 10-11, 25, claim 27 and dependent claims 28-29, claim 30 and dependent claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1, or the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1, and a method for detecting prostate cancer, comprising detecting an increased content of said nucleic acid, **does not reasonably provide enablement for 1) a nucleic acid that "comprises" a sequence that is completely complementary to the sequence of SEQ ID NO:1, or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1, and a method for detecting prostate cancer, comprising detecting an increased content of said nucleic acid, and 2) a nucleic acid molecule "having" a sequence that is**

completely complementary to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 17 and dependent claims 2-3, claim 18, claim 19 and dependent claims 10-11, 25, claim 27 and dependent claims 28-29, claim 30 and dependent claims 31-34 are drawn to:

1) A nucleic acid that "comprises" a sequence that is completely complementary to the sequence of SEQ ID NO:1 (claims 2, 3, 17), or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1 (claims 27-29), and

A method for detecting prostate cancer, comprising detecting an increased content of said nucleic acid (claims 10-11, 19, 25, 30-34).

2) A nucleic acid molecule that consists of a fragment of SEQ ID NO:1, wherein said fragment hybridizes specifically with a nucleic acid molecule "having" a sequence that is completely complementary to SEQ ID NO:1 (claim 18),

It is noted that the language "having" in claim 18 is interpreted as having the same meaning as the open language "comprises".

Due to the language "having" or "comprises', the claims encompass unknown sequences that are attached to a sequence of any size, wherein the full length of said sequence of any size is completely complementary to the sequence of SEQ ID NO:1, or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1.

Applicants have not shown how to make and use the claimed numerous nucleic acids. For example, Applicant has not taught what the structure is for the sequences

attached to a complementary fragment SEQ ID NO:1, or what the coding regions are for these sequences, or what proteins are encoded by these sequences. Further, one could not predict what the function of the claimed nucleic acids is, and whether the claimed sequences would encode a protein having the function of the protein encoded by the full length sequence, SEQ ID NO:1, in view of teaching in the art that protein chemistry is unpredictable, and that even a single amino acid substitution or what appear to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristics of a protein (Bowie, Burgess et al , Lazar et al, Tao et al, and Gillies et al, all of record), and further in view that the above teaching of the art, although drawn to proteins, would apply as well the claimed polynucleotides, because polynucleotide sequences encode proteins.

The specification does not disclose how to make the claimed nucleic acid molecules, such that they would function or have the properties as claimed, or how to use said nucleic acid molecules if they did not have the function or properties claimed.

Further, the claimed method of detecting prostate cancer would be non-specific, because the claimed method would detect unrelated sequences, that comprise a complementary fragment of SEQ ID NO:1, and one cannot predict whether an overexpression of the detected sequences could be found in prostate cancer.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

B. If Applicant could overcome the above 112, first paragraph, claims 11, 32 are still rejected under 112, first paragraph, because the specification while being

enabled for a method for detecting prostate cancer, using a sample of prostate tissue, but lacks enablement for a method for detecting prostate cancer, using a sample that is tissue "originating" from the prostate.

Claims 11, 32 are drawn to a method for detecting prostate cancer, comprising obtaining a sample that is tissue "originating" from the prostate, and detecting an increase in the content of a nucleic acid molecule comprising SEQ ID NO:1 or the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1.

Claims 11, 32 encompass a method for detecting prostate cancer, comprising obtaining a sample that is metastasized cells "originating" from the prostate, and detecting an increase in the content of a nucleic acid molecule comprising SEQ ID NO:1 or the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1.

The specification discloses that using SEQ ID NOs:7 and 8, which are primers specific for SEQ ID NO:1 (ROO504 or PB39) (p.9), overexpression of SEQ ID NO:1 is found in prostate cancer epithelium tissue samples as compared to normal control prostate tissue (Example 3 on pages 16-17, and table 1 on page 20).

One cannot extrapolate the teaching in the specification to the scope of the claims. It is unpredictable that metastasized prostate cells still express the claimed sequences, because expression of a sequence could be lost during the progression toward metastasis, as taught by Kibel et al, Zhau et al, Cheung et al and Ren et al, all of record).

Thus in view of the above, one would not have expected that the claimed sequences are useful for diagnostic information about the presence in a subject of an invasive prostate tumor.

In view of the above unpredictability, one of skill in the art would be forced into undue experimentation in order to use the claimed invention as broadly as claimed.

REJECTION UNDER 35 USC 102(b)

1. Claims 17, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals, 1994, of record, or Hudson, T, Genbank Sequence Database (Accession G22380), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available on May 31, 1996, of record.

Claims 17, 27 are drawn to:

A nucleic acid that "comprises" a sequence that is completely complementary to the sequence of SEQ ID NO:1 (claim 17), or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1 (claims 27).

Due to the open language "comprises', the claims encompass unknown sequences that are attached to a sequence of any size, wherein the full length of said sequence of any size is completely complementary to the sequence of SEQ ID NO:1, or to the sequence of nucleotide 77 through nucleotide 1753 of SEQ ID NO:1.

The Boehringer Mannheim teaches a kit comprising random primers that encompass all possible 6-nucleotide sequences (see page 93, Catalog No. 1034 731/1006 924).

Hudson, T teaches a sequence which is 100% similar to the full length SEQ ID NO:7, from nucleotide 1 to nucleotide 22, and which is 100% similar to the full length SEQ ID NO:10, from nucleotide 1 to nucleotide 20, as shown by sequence similarity search (MPSRCH search report, 2004, us-09-743-825-7.rge, p. 1-2, and us-09-743-825-10.rge, p.1-2, of record).

In view of the above teaching, one would readily envision the claimed complementary nucleic acid.

2. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals, 1994, of record.

Claim 18 is drawn to a nucleic acid molecule that consists of a fragment of SEQ ID NO:1, wherein said fragment hybridizes specifically with a nucleic acid molecule having a sequence that is completely complementary to SEQ ID NO:1.

The Boehringer Mannheim teaches a kit comprising random primers that encompass all possible 6-nucleotide sequences (see page 93, Catalog No. 1034 731/1006 924).

Although the reference does not specifically teach that the polynucleotide sequence hybridizes specifically to SEQ ID NO:1, however, the claimed nucleic acid molecule appears to be the same as the prior art polynucleotide sequence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed

product is different from those taught by the prior art and to establish patentable diffrences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

August 08, 2005